the future for which some of the methodologies or procedures may not be technically appropriate," Pet. App. 53a, and "is not a vehicle for parties to challenge anew the Guidance itself," *id.* at 54a. EPA observed in that regard that "[t]he public had a full opportunity to provide its views on [EPA's WET procedure] during the rulemaking establishing the Guidance, and the time period for challenging the Guidance has passed." *Ibid.*; see 33 U.S.C. 1369(b)(1) (petition for review of EPA action must be filed in the appropriate court of appeals within 120 days after the challenged action).

EPA further observed that, even if the scientific-indefensibility exclusion could be applied to WET, neither Indiana nor any other Great Lakes State had "actually proposed an alternative approach of projecting effluent toxicity that attempts to meet even the basic parameters of the Guidance." Pet. App. 55a. EPA explained:

> [T]he procedures submitted by Ohio, Michigan and Indiana do not address in any manner the underlying premise of [EPA's WET procedure]—that effluent quality is variable and, therefore, a method for assessing WET data must account for the likelihood that the maximum value in a particular data set is less than the true maximum that is likely to be experienced by the environment as a result of the discharge. In evaluating the potential for a discharge to cause or contribute to an exceedance of water quality standards, EPA believes it prudent to employ a procedure that minimizes the likelihood of misclassifying a discharge as not needing an effluent limitation, given the potential in such circumstances for unacceptable adverse impacts on the aquatic resource.

Id. at 54a-55a. That approach, EPA explained, will "allow the permitting authority to make a decision that will protect water quality with a high degree of confidence in the face of uncertainty and with a relatively small data set." *Id.* at 55a.

By contrast, EPA observed, the WET procedures that Indiana proposed would have "move[d] in the opposite direction by averaging the observed effluent data." Pet. App. 55a. In EPA's view, the State's proposed WET procedures ignored "the fact that a small number of data sets may not capture the worst case effluent quality," and those procedures would have allowed discharges to occur even in situations "where available data ha[ve] indicated unacceptable toxicity." *Id.* at 55a-56a. Therefore, in addition to being inconsistent with the Guidance, EPA concluded that Indiana's proposal would not be "in accordance with applicable national regulations." *Id.* at 56a (citing 40 C.F.R. 122.44(d)(1)). The effect of EPA's decision was that, given the absence of an approved state alternative, the WET implementation procedures previously set forth in the Guidance apply within Indiana and other Great Lakes States. See *id.* at 61a.

3. The State of Indiana did not seek judicial review of EPA's decision disapproving the State's proposed WET implementation procedure. However, petitioner Indiana Water Quality Coalition—a coalition of industrial entities whose effluent discharges are potentially subject to regulation under the CWA—filed a petition for review in the Seventh Circuit. See Pet. App. 5a. That petition was subsequently transferred to the Sixth Circuit and consolidated with a previously filed petition for review raising similar issues with respect to implementation procedures proposed by the State of Ohio.

See *ibid.* The court of appeals denied the petitions for review. *Id.* at 1a-16a.

a. The court of appeals held that the petitions for review were timely, notwithstanding the fact that any petition for review of the Guidance itself was required to be filed within 120 days of the Guidance's promulgation in 1995. Pet. App. 7a. The court found that petitioner challenged only "the reasonableness of the EPA's finding that the Indiana * * * implementation procedures are inconsistent with the Guidance," and that petitioner did not "contest the legitimacy of the Guidance" itself. *Ibid.*

b. On the merits, the court of appeals rejected petitioner's contention that "EPA acted in an arbitrary or capricious manner in evaluating the Indiana regulatory scheme," Pet. App. 11a, and it accordingly denied the petition for review. The court explained:

> EPA acted rationally and on the basis of considerable evidence when it rejected Indiana's regulatory scheme. Given that Indiana's averaging of toxicity will call for fewer WET limits than a system using maximum values, the EPA's conclusion that the state's scheme would be less protective of the environment was far from being arbitrary or capricious.

Ibid.

The court of appeals also rejected petitioner's contention that the proposed Indiana procedures should be treated as an appropriate alternative because the WET testing procedures described in the Guidance were scientifically indefensible. Pet. App. 14a-16a. The court explained that EPA's stated purpose for adopting the scientific-indefensibility exclusion was to allow flexibility in addressing discharges of "pollutants identified *in the*

future." *Id.* at 15a (quoting 58 Fed. Reg. 20,843 (1993)) (emphasis added by court of appeals). The court also observed that the exclusion "was intended to be 'applied to a specific situation,' * * * not to a sweeping alternative regulatory scheme." *Id.* at 16a (quoting SID, C.A. App. 309).

ARGUMENT

The judgment of the court of appeals is correct and does not conflict with any decision of this Court or of any other court of appeals. The court of appeals' decision also raises no legal issue of recurring importance. Further review is not warranted.

1. Petitioner contends (Pet. 12-18) that the court of appeals erred in holding that 40 C.F.R. 132.4(h) is inapplicable to state WET testing procedures. That claim lacks merit.

a. Section 132.4(h) states that, "[f]or any pollutant other than those in Table 5 of this part for which the State * * * demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States * * * shall" apply an alternative procedure that is consistent with all applicable federal laws. On its face, the regulation simply states what options are available *if* a State validly demonstrates that a methodology or procedure set forth in the Guidance is scientifically indefensible. Section 132.4(h) does not discuss how, when, or under what circumstances a showing of scientific indefensibility may be made. And while petitioner is correct that Section 132.4(h) "contain[s] no language that limits a State's use of the scientific indefensibility provision only to pollutants identified in the future" (Pet. 15), Section 132.4(h) also contains no explicit statement that the exclusion *does* apply to pol-

lutants that were identified before the Guidance was issued. There is consequently no basis for petitioner's contention (Pet. 15) that the understanding of Section 132.4(h) reflected in the SID is "contrary to the plain language of the regulation."

b. Additional factors reinforce the reasonableness of EPA's determination that the scientific-indefensibility exclusion is inapplicable here. The Guidance itself explains that "[t]he scientific, policy and legal basis for EPA's development of each section of the final Guidance * * * is set forth in" supporting documents that include the SID. 40 C.F.R. 132.1(b). Section 132.1(b) further states that "EPA will follow the guidance set out in these documents in reviewing the State * * * water quality programs in the Great Lakes." *Ibid.*

The text of the pertinent regulations thus expressly identifies the SID as an aid to the understanding and implementation of the Guidance. In addition, the SID was issued contemporaneously with the Guidance itself, and EPA's understanding that the scientific-indefensibility exclusion would be applicable only to subsequently-identified pollutants was clearly reflected in the proposed Guidance previously issued for public comment in 1993.[1] Contrary to petitioner's contention (Pet. 17), treating EPA's adherence to that understand-

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[1] Petitioner suggests (see Pet. 6, 12, 16) that the public did not receive notice of, and an opportunity to comment on, EPA's current interpretation of the scientific-indefensibility exclusion. That is incorrect. In issuing the proposed Guidance for public comment in 1993, EPA made clear that the exclusion was designed to address situations in which methodologies or procedures set forth in the Guidance proved to be inappropriate for newly discovered pollutants. See Pet. App. 15a-16a (quoting explanation of the exclusion given in the proposed Guidance, 58 Fed. Reg. 20,843 (1993)).

ing as permissible in no way suggests that an agency may circumvent notice-and-comment requirements by effectively amending its published regulations under the guise of re-interpretation.

Accepting petitioner's interpretation of the scientific-indefensibility exclusion would also be in tension with the statutory mandate that judicial challenges to EPA actions implementing the CWA—including the Guidance promulgated pursuant to Section 118—must be asserted promptly. See 33 U.S.C. 1369(b)(1); p. 9, *supra*. In holding that the petition for review in the instant case was timely filed, the court of appeals accepted petitioner's contention that the petition challenged only EPA's *application* of the Guidance to Indiana's proposed regulatory scheme. See Pet. App. 7a. An argument that the Guidance methodology is scientifically indefensible as applied to a newly-identified pollutant might plausibly be characterized in that manner. But petitioner's contention that the Guidance methodology is scientifically indefensible as applied to a pollutant that was known and specifically addressed at the time the Guidance was issued is much more naturally characterized as a challenge to the Guidance itself. That is particularly so in light of the fact that petitioner challenges the Guidance's WET implementation procedures "on their face," rather than as applied to a particular factual setting. See *id.* at 16a (noting that EPA intended the scientific-indefensibility exclusion to apply to a "specific situation," rather than to the sort of "sweeping alternative regulatory scheme" that petitioner advocates).[2]

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[2] The Guidance itself was previously challenged in court and was upheld in most respects. See *American Iron & Steel Inst.* v. *EPA*, 115 F.3d 979 (D.C. Cir. 1997).

2. In the administrative decision at issue in this case, EPA also explained that, *even if* the scientific-indefensibility exclusion were potentially applicable to WET testing procedures, Indiana's proposal would be rejected because the State's approach was insufficiently protective of aquatic resources and was not "in accordance with applicable national regulations." Pet. App. 56a (citing 40 C.F.R. 122.44(d)(1)); see *id.* at 54a-56a. Because a Great Lakes State that seeks to invoke the scientific-indefensibility exclusion must offer "an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws," 40 C.F.R. 132.4(h)(2), EPA's assessment of the shortcomings of Indiana's proposal provides an independent basis for the administrative action that is currently under review. And while the court of appeals' discussion of the scientific-indefensibility exclusion (see Pet. App. 14a-16a) did not refer to that aspect of EPA's rationale, the court had previously expressed general approval of EPA's scientific analysis. See Pet. App. 9a-11a.[3] There is consequently no reason to believe that the court of appeals' *judgment* denying the petition for review would have been affected if the court had rejected EPA's interpretation of 40 C.F.R. 132.4(h).

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[3] The court of appeals concluded that

> the EPA acted rationally and on the basis of considerable evidence when it rejected Indiana's regulatory scheme. Given that Indiana's averaging of toxicity will call for fewer WET limits than a system using maximum values, the EPA's conclusion that the state's scheme would be less protective of the environment was far from being arbitrary or capricious.

Pet. App. 11a.

3. For other reasons as well, petitioner's challenge to EPA's interpretation of its own regulation does not warrant this Court's review.

a. In its discussion of the scientific-indefensibility exclusion (Pet. App. 14a-16a), the court of appeals did not announce any general rule defining the circumstances under which documents like the SID may be consulted, or the weight that they should be given, when a court interprets published agency regulations. There is consequently no basis for petitioner's concern (see Pet. 17) that the Sixth Circuit's decision may be cited in future cases as authority for the proposition that informal agency guidance can supersede unambiguous regulatory text. Nor is there any basis for petitioner's claim (Pet. 12, 15-16) that the decision below conflicts with decisions in which other courts of appeals have interpreted other agency regulations in accordance with their plain language. The court of appeals did not hold or suggest that EPA's interpretation is inconsistent with any unambiguous regulatory text, and thus petitioner's claim of a conflict rests on a mistaken premise.

b. The statutory and regulatory provisions that govern the disposition of this case are unusual, and the practical significance of the court of appeals' decision is accordingly limited. Section 118 of the CWA, 33 U.S.C. 1268 (2000 & Supp. III 2003), applies only to States surrounding the Great Lakes. The EPA action at issue here applies by its terms only to activities conducted in Indiana that result in discharges of pollutants to Lake Michigan and its tributaries. See 33 U.S.C. 1268(a)(3)(C); 40 C.F.R. 132.6(c). The instant case, moreover, is the only one in which a court has reviewed an application of EPA's "final water quality guidance" to a Great Lakes State, see 33 U.S.C. 1268(c)(2)(B), and it

is unlikely that another such case will arise in the future, since the deadline for Great Lakes States to submit their water quality programs for review by EPA expired long ago, see 33 U.S.C. 1268(c)(2)(C), and EPA completed its review of those programs in 2000. See Pet. App. 19a-65a.

In addition, Section 118's directive that EPA provide "guidance" to state regulators is itself an unusual statutory mandate. As the court explained in *American Iron & Steel Inst.* v. *EPA*, 115 F.3d 979 (D.C. Cir. 1997), the Guidance issued by EPA in 1995 "certainly restricts state flexibility, but it does not immediately impose any requirements. It merely announces the standards by which state submissions will be judged and informs the states of the default rule that the agency will apply if a state submits a nonconforming plan." *Id.* at 988. Because the CWA requirement that EPA provide "guidance" to Great Lakes States and Tribes is essentially *sui generis*, this case would not present a suitable vehicle for addressing more general questions concerning federal agencies' efforts to clarify published regulations by incorporating contemporaneously issued, but less formal, explanatory documents.

c. In the decision at issue here, EPA disapproved limited aspects of the Great Lakes program adopted by the State of Indiana. The State did not petition for review of the EPA decision, nor did it intervene in the Sixth Circuit proceeding. Rather, in both the court of appeals and in this Court, EPA's action with regard to the Indiana proposal has been challenged solely by a coalition of regulated private entities. The State's acquiescence in EPA's decision provides a further reason for concluding that the question presented here does not warrant this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE

Supreme Court of the United States

INDIANA WATER QUALITY COALITION,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioner's corporate disclosure statement was set forth at page *ii* of its Petition for a Writ of Certiorari, and there are no amendments to that statement.

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Petitioner, the Indiana Water Quality Coalition ("IWQC"), seeks to preserve the uniformity of long-standing principles of administrative law that prohibit deference to an agency's interpretation of unambiguous language in a regulation. This Court's review is necessary to confirm the principles established by this Court, and to address the conflict created by the Sixth Circuit Court of Appeals' departure from the accepted and usual course of judicial proceedings.

Despite its efforts to distance itself from the well-established administrative law governing the interpretation of unambiguous regulations, the United States Environmental Protection Agency ("EPA") cannot escape the reality that 40 C.F.R. § 132.4(h) ("section 132.4(h)") is unambiguous on its face and not subject to EPA's interpretation beyond the regulation's plain terms. In its attempt to avoid this fact, EPA fails to offer any interpretation of section 132.4(h) that would render its terms ambiguous and, thus, subject to interpretation through informal agency documents. Instead, EPA seeks to legitimize the Sixth Circuit's decision by unilaterally creating a new exception to the interpretive principles set forth in *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). This exception has never been invoked by any court, including the Sixth Circuit in this case. In asserting this exception, EPA erroneously claims that because 40 C.F.R. § 132.1(b) ("section 132.1(b)") refers to informal support documents that were used to develop the scientific, policy, and legal basis for the *Final Water Quality Guidance for the Great Lakes System*, 60 Fed. Reg. 15,366 (March 23, 1995) (the "GL Guidance"), such informal documents must be given deference regardless of the unambiguous language of section 132.4(h).

EPA, however, ignores the fact that courts are bound by the language of unambiguous regulations without exception. EPA's unsupported arguments demonstrate the degree by which the Sixth Circuit departed from the usual course of judicial proceedings. The Sixth Circuit's disregard of the unambiguous language of section 132.4(h) violates fundamental principles of administrative law, and review is necessary to prevent the recurring misapplications of this law that will be caused if the Sixth Circuit's decision is left to stand.

THE SIXTH CIRCUIT'S DECISION DEPARTS FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDINGS.

A. The Sixth Circuit's decision disregarded the unambiguous language of section 132.4(h).

Notably, EPA fails to rebut the fact that the unambiguous language of section 132.4(h) includes the pollutant whole effluent toxicity ("WET") within its scope. In fact, EPA admits that "WET is not one of the pollutants listed in Table 5 of Part 132." Opp. 5. Section 132.4(h) states:

> **For any pollutant other than those in Table 5 of this part** for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:
>
> (1) Apply an alternative methodology or procedure acceptable under 40 C.F.R. part 131 when developing water quality criteria; or

> (2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

40 C.F.R. § 132.4(h) (emphasis added). Because section 132.4(h) applies to pollutants "other than those in Table 5 of" Part 132, the only possible interpretation of this language is that section 132.4(h) applies to WET. There is no other language in section 132.4(h) that could arguably affect the scope of this unambiguous regulation. In the absence of any ambiguity in the regulatory language, EPA's interpretation is irrelevant.

Despite this clear language, EPA argues that, while section 132.4(h) does not state that it only applies to pollutants identified in the future, section 132.4(h) also does not state that it "*does* apply to pollutants that were identified before the Guidance was issued." Opp. 10-11 (emphasis in original). This argument states the obvious and proves IWQC's point. It is not disputed that section 132.4(h) neither states that it applies exclusively to pollutants identified when the GL Guidance was passed nor that it applies exclusively to pollutants identified in the future. The only reasonable conclusion to be drawn from this absence of language is that section 132.4(h) applies to all pollutants regardless of when they were or are identified, so long as they are not included in Table 5. EPA is attempting to use this absence of language to create an ambiguity in section 132.4(h). But if EPA's argument were extended to its logical conclusion, any regulation could be considered ambiguous if it did not expressly state the implicit notion that it applies to everything but what is explicitly excepted.[1] Despite EPA's efforts, the only limitation

1. For example, if an agency issued a regulation that prohibited the sale of widgets, EPA would argue that the regulation is ambiguous

(Cont'd)

on the scope of section 132.4(h) is that it does not apply to pollutants listed in Table 5 of Part 132 of Title 40 of the federal regulations. WET is not listed in Table 5, and is, therefore, covered by section 132.4(h).

B. The Sixth Circuit's decision creates a *de facto* regulation using informal agency documents in violation of *Christensen*.

EPA also seeks to legitimatize the Sixth Circuit's reliance on informal agency documents to revise the unambiguous language of section 132.4(h). Specifically, EPA claims that the Sixth Circuit properly deferred to EPA's interpretation limiting section 132.4(h) to pollutants identified in the future based on the EPA document *Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID)* (EPA 820-B-95-001, March 1995) (the "SID"), because another regulation refers to the SID as providing a partial basis for the GL Guidance. Opp. 11; 40 C.F.R. § 132.1(b) ("The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the . . . [SID] . . ."). EPA also argues that the Sixth Circuit could defer to EPA's interpretation as set forth in the SID because section 132.4(h) and the SID were issued contemporaneously. *Id.* Neither argument has merit.

(Cont'd)

because it neither states that it applies only to new widgets nor that it does apply to used widgets. Clearly, such a regulation is not ambiguous, as it would apply to all widgets regardless of their date of production. The danger of EPA's argument is that if it is accepted, every federal regulation would arguably be rendered ambiguous.

If EPA is allowed to use a mere reference to the SID in section 132.1(b) to overcome the unambiguous language of section 132.4(h), such a policy would abrogate the principles of regulatory construction set forth in *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). Without exception, this Court held in *Christensen* that a court can defer to an agency's interpretation of a regulation "only when the language of the regulation is ambiguous." *Christensen*, 529 U.S. at 588. Otherwise, "[t]o defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation." *Id.* In this case, EPA is attempting to create such a *de facto* regulation. In essence, EPA claims that if it references an informal agency document, such as the SID,[2] in a regulation, that agency document somehow attains the same legal status as the regulation itself. In other words, the reference to an informal agency document in a regulation should create *de facto* a new regulation encompassed in the agency document, in this case a 497-page technical document.

EPA takes the argument one step further, claiming that the *de facto* regulation in the SID should control over all other unambiguous regulations that are part of the GL Guidance regulatory scheme, including section 132.4(h). EPA makes this argument without citing any case law that would support the existence of its "cross-reference" exception to the doctrine set forth in *Christensen*. Indeed, there is no case law to support such an exception. As a policy matter, such an exception would negate the due process protections that govern agency rulemaking. If EPA's "cross-reference"

2. The SID is a 497-page technical document that was not subjected to review under the federal Administrative Procedure Act, 5 U.S.C. § 500, *et seq*. Instead, the SID was reviewed only by EPA's Office of Science and Technology. *See* SID, § DISCLAIMER.

exception became law, agencies could contradict the plain language of any regulation simply by including a reference to a guidance document without adopting that document as a formal rule. Such an exception would swallow the fundamental rule provided by this Court in *Christensen*. In addition, there is no case law or policy reason that supports EPA's argument that because the SID was issued contemporaneously with the GL Guidance, the SID is entitled to special deference in interpreting the unambiguous language of section 132.4(h). In the end, the SID, having been informally published by EPA, is not entitled to the deference the Sixth Circuit accorded it. *See Christensen*, 529 U.S. at 587 (Interpretations based on agency opinion letters, policy statements, agency manuals, and enforcement guidelines, "all of which lack the force of law — do not warrant *Chevron*-style deference."); s*ee also*, *Navarro v. Pfizer Corp.*, 261 F.3d 90, 103 n. 7 (1st Cir. 2001) ("We wish to make clear that even if *Chevron* applied, we still would not defer to the EEOC interpretive guidance because the regulation in question is not ambiguous."); *Clean Ocean Action v. York*, 57 F.3d 328, 333-34 (3rd Cir. 1995) ("Thus [EPA's] Green Book is merely a guidance document which cannot be given the effect of amending the Regulations."); *Echevarria v. Chicago Title & Trust Co.*, 256 F.3d 623, 629 (7th Cir. 2001) ("Reviewing the language and the stated purpose of Regulation X, we conclude that it is not ambiguous, and we therefore owe the opinion letters and special informational booklet no extra deference.").

In its efforts to change the language of section 132.4(h) by using the SID, EPA ignores the obvious question in this case: if it wanted section 132.4(h) to apply only to pollutants identified in the future, why did EPA not include such limiting language in section 132.4(h) itself? If EPA intended section

132.4(h) to be limited only to pollutants identified in the future, it was free to propose and adopt such limitation explicitly in the language of the regulation. In the absence of such language, the Sixth Circuit was not free to read such a limitation into the unambiguous language. *Christensen*, 529 U.S. at 588 (A court can defer to an agency's interpretation of a regulation "only when the language of the regulation is ambiguous.").

In addition, EPA argues that because the preamble to the *Proposed Water Quality Guidance for the Great Lakes System*, 58 Fed. Reg. 20,802, 20,843 (April 16, 1993) (the "Proposed Guidance") provided that section "132.4(g)" (later to become section 132.4(h)) may apply only to pollutants identified in the future, IWQC should know that section 132.4(h) is limited as provided in the SID. Opp. 11. Again, this allegation ignores *Christensen* and its progeny. The unambiguous language of section 132.4(h) makes no reference to being limited to pollutants identified in the future. In fact, similar to section 132.4(h), the proposed language in section 132.4(g) of the Proposed Guidance did not contain any limitations indicating that it only applied to pollutants identified in the future. 58 Fed. Reg. at 21,013 ("For pollutants listed in Table 5 of this part, or for any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that one or more methodologies or procedures in this part are not scientifically defensible . . ."). Regardless, an agency's interpretation that is stated in a preamble of a regulation is irrelevant for interpreting the unambiguous language of the regulation. *See, e.g., Yazoo R.R. Co. v. Thomas*, 132 U.S. 174, 188 (1889); *Beard v. Rowan*, 34 U.S. 301, 317 (1835); *Entergy Servs., Inc. v. FERC*, 375 F.3d 1204, 1209 (D.C. Cir. 2004).